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HEADLINE: Corporate News: FDA Warns Glaxo Over Lack of Reports on Avandia

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BODY:

The Food and Drug Administration issued a stern warning letter to GlaxoSmithKline PLC, saying the drug maker failed to file regular reports to the agency about clinical trials it was carrying out on its diabetes drug, Avandia, as required by law.

The FDA called the violations "serious" and ordered Glaxo to take prompt action to prevent future transgressions. The agency said it requires companies to report regularly on clinical trials so that it can spot potential safety problems with drugs. The FDA uncovered Glaxo's violations during an inspection last year of the company's records, according to the letter, which was addressed to Glaxo Chief Executive Jean-Pierre Garnier and posted on the FDA's Web site Tuesday.

Avandia has been under scrutiny since last year, when a study concluded that patients taking the drug had a higher risk of suffering a heart attack than those taking other oral diabetes medicines or placebo pills. In November, the FDA ordered Glaxo to add a "black-box" warning to Avandia's label describing the study's findings. The drug's sales have plunged since the controversy started.

According to the FDA's warning letter, the agency began inspecting Glaxo records in August to check whether the company was reporting all Avandia data in full. It found that between 2001 and 2007, Glaxo failed to tell the FDA about the initiation of nine clinical studies, and failed to update the FDA about the progress of more than a dozen other studies.

The FDA letter doesn't say whether the agency would have taken different action on Avandia had it had the missing information in hand earlier. However, Susan Cruzan, an FDA spokeswoman, said while Glaxo failed to meet some administrative requirements about reporting the status of post-marketing studies, the company has submitted the safety information for the completed studies. Ms. Cruzan said the "results did not change FDA's determination" that there is "inconclusive" evidence about an increased risk of heart attacks.

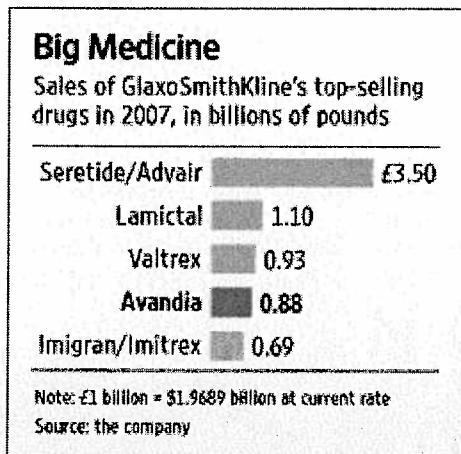
Glaxo spokeswoman Nancy Pekarek called the missing reports "inadvertent omissions."

She said Glaxo provided the FDA with all of the missing information in September. "It was in the hands of the FDA before they made their decision on" adding a black box to Avandia's label, she said. "They had all the information they needed to inform their decision making on the label," she said.

Ms. Pekarek added that Glaxo has started training relevant staff so that they know "what they're supposed to report, when they're supposed to report it and how they're supposed to report it."

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The FDA issues a few dozen warning letters each year to various drug companies. Companies usually comply with the agency's demands, but if they don't the FDA can fine the companies or slap them with other penalties.



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